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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/634,206	08/05/2003	Russell Powers	MSDI-196/PC934.00	6826

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KRIEG DEVAULT LLP
ONE INDIANA SQUARE, SUITE 2800
INDIANAPOLIS, IN 46204-2709

EXAMINER	
PELLEGRINO, BRIAN E	
ART UNIT	**PAPER NUMBER**
3738	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/634,206	POWERS ET AL.	
	Examiner	Art Unit	
	Brian E Pellegrino	3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 July 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *3,5-20,22-28,30,31,33-39 and 56-72* is/are pending in the application.

4a) Of the above claim(s) *10-16,18,19,27,28,30,31,33-39 and 56-72* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *3,5-9,17,20 and 22-26* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: the limitation that the components and instrumentation within a single container are to perform a designated spinal stabilization procedure was not found in the written description. While the components disclosed may be used to stabilize the spine, there was no description of what stabilization procedures are defined as or specifically have to include in this type of surgical repair.

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 3,17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy (6273916). Henniges et al. shows (Fig. 1) a surgical plate **10** and a number of bone screws **12** to secure the plate. Fig. 11A shows a driver instrument **24** with a shaft or first portion **372** and a second handle portion **15** and an end portion to drive the screws into bone. Henniges et al. disclose the equipment is packaged, paragraph 60. Fig. 31 shows the components for a stabilization surgery in a packaged kit with the driver being multi-piece. However, Henniges fails to specifically disclose the spinal plate, screws and instrumentation in a *single container*

and in sterile condition. Murphy teaches a surgical kit for spinal surgery including all the components in a single container and sterile condition and is designed that if certain components are not used they could be saved for a future surgery, col. 3, lines 6-10, col. 4, lines 31-37. Murphy shows (Fig. 4) the spinal surgery kit includes all components and separate compartments, including instrumentation. It would have been obvious to one of ordinary skill in the art to use a "single container" for the spinal surgery kit as taught by Murphy with the spinal plate, screws and instrumentation of Henniges et al. so that it reduces the packaging used and costs involved in manufacturing the kit and provides all the components required for easy retrieval by the surgeon.

Claim 20 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/107574) in view of Murphy '916 as applied to claim 17 above, and further in view of Sweeny (5901622). Henniges et al. in view of Murphy is explained as before. However, Henniges et al. as modified by Murphy fail to disclose the shaft being mulit-piece or having multi-functions. Sweeny shows (Fig. 4) a reversible shaft with two different tip sizes. The driver thus is fully capable of performing "multiple functions". Sweeny also teaches that the use of reversible shafts provides multiple functions, which is advantageous, col. 1, lines 23-27. It would have been obvious to one of ordinary skill in the art to provide a multi-function shaft as taught by Sweeny with the instrument in the kit of Henniges as modified by Murphy such that the surgeon is able to use the same instrument without having to get another instrument when adjusting for different size screws.

Claims 5,6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Ray (2001/20185). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to disclose an interbody implant with the spinal plate device. Ray teaches interbody implants are placed between first and second vertebrae, paragraph 20. Ray shows (Fig. 2) a plate member and an interbody implant (Fig. 3) that are part of a "kit" used together as shown in Fig. 1. It would have been obvious to one of ordinary skill in the art to include an interbody implant for fusing vertebrae with a plate member as taught by Ray into the kit of Henniges et al. in view of Murphy such that it enables the surgeon to correct for weakened vertebrae and provides more stabilization.

Claims 7-9 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Wagner et al. (5306309). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to disclose instruments designed for disposal or single use. Wagner teaches that an instrument for spinal surgery is used and designed for planned disposal, col. 4, lines 9,10. It would have been obvious to one of ordinary skill in the art to utilize a discardable instrument as taught by Wagner et al. for the driver of Henniges et al. as modified by Murphy such that no germs, bacteria etc. can be spread to another patient by providing an instrument to discard or one time use.

Claims 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Paikoff et al. (4523679). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to specifically disclose a plurality of compartments to hold the kit components or that there is an inner and outer container to maintain sterility or that the packaging is clear. Paikoff et al. show packaging for medical instrumentation with a plurality of compartments. Paikoff also teaches that the packaging is formed with an inner and outer container, col. 3, lines 55-65, col. 4, lines 38-43. It is also well known that the plastic is clear such that the surgeon can see what is in the package. Paikoff additionally teaches that the different compartments are used to allow for different sterilized products, col. 3, lines 42-45,65-68. It would have been obvious to one of ordinary skill in the art to use multi compartments as taught by Paikoff to package the spinal kit of Henniges et al. as modified by Murphy so that no damage is done to the different components of the kit while packaged and sterilized under sterilization procedures.

Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over Henniges et al. (2002/4660) in view of Murphy '916 as applied to claim 3 above, and further in view of Banick et al. (2003/93153). Henniges et al. in view of Murphy is explained supra. However, Henniges et al. as modified by Murphy fail to disclose a template with images. Banick et al. show (Fig. 7) a surgical kit **60** for use in spinal surgery comprising spinal components and a template. It is well known that templates or instructions include images of apparatus of use for surgeries. It would have been

obvious to one of ordinary skill in the art to include a template with images as taught by Banick et al. in the kit of Henniges et al. as modified by Murphy such that it enables a surgeon or doctor to be provided with dimensions of the device for consideration after possibly making measurements or evaluation of the patient's anatomical implantation site.

Response to Arguments

Applicant's arguments filed 7/6/07 have been fully considered but they are not persuasive. In response to applicant's arguments against Henniges and Murphy individually, one cannot show nonobviousness by attacking references individually where the rejections are based on combinations of references. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981); *In re Merck & Co.*, 800 F.2d 1091, 231 USPQ 375 (Fed. Cir. 1986). Applicant argues that Henniges does not disclose packaging components for a spinal surgery together. However, as mentioned above Henniges shows components together to form a kit, but does not specifically describe this since it is known to one of ordinary skill in the art. Murphy supports this conclusion and is used for the teaching of having the components together in a kit for that surgery. Applicant argues Murphy teaches a different procedure, however, this is irrelevant. Additionally, the Examiner is not giving any special definition to "stabilization procedure" as this can be interpreted many ways in the spinal repair area of expertise. For example placing an intervertebral device between vertebrae stabilizes a weakened nucleus or

collapsing vertebrae. Rods and screws are other stabilization components used in spinal repair. Thus, stabilization procedures are not limited to **plates**.

Applicant also argues that Henniges cannot be combined with Ray since Ray does not disclose the components in a kit or packaging. Again as mentioned above it is understood or well known that these are packaged, no surgeon would risk liability and have a surgical implant to use with a patient that is not packaged. Additionally, the rejection is based on the combination not on individual references which are being piecemeal analyzed. Henniges provides the concept of packaging in a kit and Ray further teaches that interbody implants are known to be used with plates exteriorly or not between the spine. Thus, the combination is obvious.

With respect to claims 7-9,22-25 since there was no disagreement with the examiner's contentions about the Wagner and Paikoff teachings, they must be obvious to one of ordinary skill in the art in modifying a surgical stabilization kit. Applicant failed to discuss these references applied against the claims, explaining how the claims avoid the references or distinguish from them. These rejections are maintained.

Applicant also argues that the combination of Henniges and Murphy and Banick would not include images on a template or instructions. However, it is the Examiner's position that instructions do show images of how apparatus is often assembled and used, thus images are necessary to give a clear understanding. Thus the rejection is proper.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian E Pellegrino whose telephone number is 571-272-4756. The examiner can normally be reached on M-Fr (8:30am-5pm). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached at 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Brian E Pellegrino

BRIAN E. PELLEGRINO
PRIMARY EXAMINER